Notice of Allowability	Application No.	Applicant(s)	
	10/820,099	MCEWEN, SIMON	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the interview of 10/22/2010*.

2. ☒ The allowed claim(s) is/are *1,4,9-11,14-16,19-23,29,30 and 33*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20101020* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Irene Marx/
Primary Examiner, Art Unit 1651

Election/Restrictions

Claims 1, 4-6, 9-16, 18-24 and 29-33 are pending.

Claims 1, 4, 9-11,14-16, 19-23, 29 and 33, as amended below, are allowable. The restriction requirement between Groups I and II, as set forth in the Office action mailed on 10/5/2006, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 30 and 31, directed to a method for using the composition of claims 1, 11 or 29 for the treatment of rheumatoid arthritis are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim. However, claim 32, directed to a composition for the treatment of multiple sclerosis remains withdrawn from consideration because it does not require all the limitations of an allowable claim. It is noted that claim 32 was added in the response filed 10/28/2009 but was withdrawn based on election by original presentation in the Office action mailed 2/19/2010.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Peter Lauro on 10/22/2010. Mr. Lauro authorized the payment of any additional fees incurred by the addition of the multiple dependent claim to deposit account 04-1105.

The application has been amended as follows:

IN THE TITLE

The title was replaced by the following:

--Therapeutic Composition for the Treatment of Rheumatoid Arthritis --

IN THE SPECFICATION

The following was inserted after line 22 which reads "sulphate." on page 5:

-- A preferred embodiment is a composition comprising 1,000 to 5,000 Fishman units/ml β-glucuronidase, 6 µg/ml protamine sulphate, 1 µg/ml 1,3 cyclohexane diol, and 0.5 mg/ml chondroitin sulphate, and collagen present in a concentration selected from the group consisting of 2.5×10^{12}, 2.5×10^{10} and 2.5×10^{4} molecules/ml buffered to a pH of 5.9.--

All text and the picture on pages1-4 of the appendix to the specification filed 10/28/09 were deleted.

IN THE ABSTRACT

The abstract was replaced by the following:

--A therapeutic composition and a method for rheumatoid arthritis is described. The composition comprises purified beta-glucuronidase at a concentration of between 200 and 10,000 Fishman units/ml and purified collagen at a concentration of between 0.5 and 2.5 mg/ml. The composition is administered by transdermal infusion or intradermal injection. --

IN THE CLAIMS

Claims 5, 6, 18, 24, 31 and 32 have been cancelled.

Claim 1 was replaced by the following:

-- 1. A therapeutic composition for the treatment of rheumatoid arthritis, wherein the composition comprises ~~a~~ purified beta-glucuronidase at a concentration of between 200 and 10,000 Fishman units/ml and purified collagen at a concentration of between 0.5 and 2.5 mg/ml, wherein the composition is at a dose that provides a beneficial effect to an individual in need of treatment of rheumatoid arthritis. --

Claim 4 was replaced by the following:

--4. The composition of claim 1, wherein the beta-glucuronidase is beta-D-glucuronoside glucuronosohydrolase (EC 3.2.1.31). --

Claims 9-11 were replaced by the following:

-- 9. The composition of claim 1, further comprising protamine sulphate or 1,10-diamino decane.

10. The composition of claim 9, wherein the protamine sulphate or 1,10-diamino decane is present at a concentration of 3-9 mg/L.

11. A therapeutic composition for the treatment of rheumatoid arthritis, the composition comprising a purified beta-glucuronidase at a concentration of between 200 and 10,000 Fishman units/ml, purified collagen at a concentration of between 0.5 and 2.5 mg/ml, and 1,3 cyclohexane diol and either protamine sulphate or 1,10-diamino decane in which the beta-glucuronidase and the collagen are present in the composition at a dose which provides a beneficial effect to an individual in need of treatment rheumatoid arthritis. --

Claim 14 was replaced by the following:

-- 14. The composition of claim 11, wherein the protamine sulphate or 1,10 diamino-decane is present at a concentration of 3-9 µg/ml and the cyclohexane diol is present at a concentration of 1 µg/ml. --

Claims 20 and 21 were replaced by the following:

-- 20. The composition according to claim 19, wherein the glycosaminoglycan is selected from the group consisting of hyaluronate, chondroitin sulphate, dermatan sulphate, keratan sulphate and heparan sulphate.

21. The composition of claim 19, wherein the glycosaminoglycan is chondroin-6-sulphate. --

Claims 29 and 30 were replaced by the following:

-- 29. A composition for the treatment of rheumatoid arthritis comprising 1,000 to 5,000 Fishman units/ml β-glucuronidase, 6 µg/ml protamine sulphate, 1 µg/ml 1,3 cyclohexane diol, and 0.5 mg/ml chondroitin sulphate and collagen present in a concentration selected from the group consisting of 2.5×10^{12}, 2.5×10^{10} and 2.5×10^{4} molecules/ml buffered to a pH of 5.9.

30. A method for the treatment of rheumatoid arthritis comprising administering by transdermal infusion or intradermal injection an effective amount of a composition of claims 1, 11 or 29 to ameliorate a symptom of rheumatoid arthritis to an individual in need thereof. --

Claim 33 was replaced by the following:

-- 33. The composition of claim 20, wherein the hyaluronate is D-glucuronic acid-N-acetyl-D-glucosamine; the chondroitin sulphate is D-glucuronic acid-N-acetyl-D-galactosamine 4- or 6-sulphate; the dermatan sulphate is D-glucuronic acid or L iduronic acid N-acetyl-D- galactosamine; the keratan sulphate is D-galactose-N-acetyl-D- glucosamine sulphate; and the heparan sulphate is D-glucuronic acid or L-iduronic acid N-acetyl-D-glucosamine. --

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Irene Marx/
Primary Examiner
Art Unit 1651